Cigna National Formulary Coverage Policy

Effective Date **4/1/2023**
Next Review Date **4/1/2024**

Drug Quantity Management – Per Rx
Antiseizure Medications – Vigabatrin

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Product Identifier(s)

131858

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Sabril® (vigabatrin tablets and powder for oral solution – generic)
- Vigadrone® (vigabatrin powder for oral solution – [generic to Sabril powder for oral solution])

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of vigabatrin. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Sabril® (vigabatrin tablets and powder for oral solution, generic)	500 mg tablets	180 tablets	540 tablets
	500 mg powder packets	150 packets	450 packets
Vigadrone®	500 mg powder packets	150 packets	450 packets

(vigabatrin powder for oral solution)			

Cigna covers quantities as medically necessary when the following criteria are met:

Vigabatrin 500 mg tablets (Sabril, generic)

1. If an individual requires a dose of more than 3,000 mg per day, approve the requested quantity not to exceed 360 tablets per dispensing at retail or 1,080 tablets per dispensing at home delivery.
   Note: This override allows for dosing up to 6,000 mg per day.

Vigabatrin 500 mg powder packets (Sabril, generic) and Vigadrone 500 mg powder packets

1. If an individual requires a dose of more than 2,500 mg per day, approve the requested quantity not to exceed 350 packets per dispensing at retail or 1,050 packets per dispensing at home delivery.
   Note: This override allows for dosing up to approximately 6,000 mg per day, rounded to the nearest 50 packet carton.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Vigabatrin, an antieseizure medication, is indicated for the following uses:[1]

- **Refractory complex partial seizures** as adjunctive therapy in adults and pediatric patients ≥ 2 years of age who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss. Vigabatrin is not indicated as a first line agent for complex partial seizures.
- **Infantile spasms** as monotherapy in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss.

Dosing and Administration

Vigabatrin's dosing regimen depends on the indication, age group, weight, and dosage form (i.e., tablets or powder for oral solution).[1] Patients with impaired renal function require dose adjustment. Vigabatrin may be taken with or without food. Vigabatrin powder for oral solution should be mixed with water prior to administration. A calibrated measuring device is recommended to measure and deliver the prescribed dose accurately. A household teaspoon or tablespoon is not an adequate measuring device. When discontinuing vigabatrin, the dose should be gradually reduced.

Refractory Complex Partial Seizures

Adults (Patients ≥ 17 Years of Age)

Treatment with vigabatrin should be initiated at 1,000 mg/day (500 mg twice daily [BID]).[1] Total daily dose may be increased in 500 mg increments at weekly intervals, depending on response. The recommended dose of vigabatrin in adults is 3,000 mg/day (1,500 mg BID). However, doses up to 6,000 mg have been studied.[1,3] According to current guidelines, vigabatrin doses of 1 , 3, and 6 grams per day yielded significant higher responder rates and larger reductions in monthly seizure frequency.[3] Fatigue and drowsiness are the most frequent adverse events, with higher drug discontinuation in the 6 gram per day group.

Pediatric (Patients 2 to 16 Years of Age)

The recommended dosage of vigabatrin is based on body weight and administered as two divided doses.[1] The dosage may be increased in weekly intervals to the total daily maintenance dosage, depending on response (Table 1). Pediatric patients weighing > 60 kg should be dosed according to adult recommendations.

Table 1: Dosing Recommendations for Vigabatrin in Pediatric Patients Weighing 10 kg up to 60 kg.[1]

Body Weight	Recommended Total Daily Maintenance Dose
10 kg to 15 kg	1,050 mg/day
> 15 kg to 20 kg	1,300 mg/day
> 20 kg to 25 kg	1,500 mg/day
> 25 kg to 60 kg	2,000 mg/day

Infantile Spasms (patients 1 month to 2 years of age)
The initial daily dosage of vigabatrin is 25 mg/kg BID (50 mg/kg/day); subsequent dosing can be titrated by 25 mg/kg/day to 50 mg/kg/day increments every 3 days, up to a maximum of 75 mg/kg BID (150 mg/kg/day) [Table 2].[1]

Table 2: Dose and Volume of Vigabatrin 50 mg/mL Solution in Infants by Weight.[1]

Infant Weight	Starting Dose 50 mg/kg/day		Maximum Dose 150 mg/kg/day	
3 kg	75 mg BID	1.5 mL BID	225 mg BID	4.5 mL BID
4 kg	100 mg BID	2 mL BID	300 mg BID	6 mL BID
5 kg	125 mg BID	2.5 mL BID	375 mg BID	7.5 mL BID
6 kg	150 mg BID	3 mL BID	450 mg BID	9 mL BID
7 kg	175 mg BID	3.5 mL BID	525 mg BID	10.5 mL BID
8 kg	200 mg BID	4 mL BID	600 mg BID	12 mL BID
9 kg	225 mg BID	4.5 mL BID	675 mg BID	13.5 mL BID
10 kg	250 mg BID	5 mL BID	750 mg BID	15 mL BID
11 kg	275 mg BID	5.5 mL BID	825 mg BID	16.5 mL BID
12 kg	300 mg BID	6 mL BID	900 mg BID	18 mL BID
13 kg	325 mg BID	6.5 mL BID	975 mg BID	19.5 mL BID
14 kg	350 mg BID	7 mL BID	1,050 mg BID	21 mL BID
15 kg	375 mg BID	7.5 mL BID	1,125 mg BID	22.5 mL BID
16 kg	400 mg BID	8 mL BID	1,200 mg BID	24 mL BID

BID – Twice daily.

Availability
Vigabatrin (Sabril, generic) is available as 500 mg film-coated tablets, scored on one side and supplied in bottles of 100 tablets.[1] Vigabatrin (Sabril, generic) and Vigadrone are available as powder for oral solution in 500 mg packets of powder and supplied in cartons of 50 packets.[1,2]

Safety
Vigabatrin can cause permanent bilateral concentric visual field constriction, including tunnel vision that can result in disability. In some cases, vigabatrin may also decrease visual acuity. Risk increases with increasing dose and cumulative exposure, but there is no dose or exposure to vigabatrin known to be free of risk of vision loss. Use the lowest dosage and shortest exposure to vigabatrin consistent with clinical objectives. In patients with refractory complex partial seizures, vigabatrin should be withdrawn if a substantial clinical benefit is not observed within 3 months of initiating treatment. If the prescriber notes evidence of treatment failure earlier than 3 months, treatment should be discontinued at that time. In patients with infantile spasms, vigabatrin should be withdrawn if a substantial clinical benefit is not observed within 2 to 4 weeks. If the prescriber notes treatment failure earlier than 2 to 4 weeks, treatment should be discontinued at that time.

References

1. Sabril® tablets and powder packets [prescribing information]. Deerfield, IL: Lundbeck; October 2021.
2. Vigadrone® powder packets [prescribing information]. Maple Grove, MN: Upsher-Smith; February 2020.
3. Kanner AM, Ashman E, Gloss D, et al. Practice guideline update summary: efficacy and tolerability of the new antiepileptic drugs II: treatment-resistant epilepsy: report of the guideline development, dissemination, and implementation subcommittee of the American Academy of Neurology and the American Epilepsy Society. *Neurology*. 2018;91(2):82-90.

Revision History

Type of Revision	Summary of Changes	Approval Date
New Policy	--	01/18/2023